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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KISH, JAMES M	

ART UNIT	PAPER NUMBER
3737	

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/690,472	SHACHAR, YEHOSHUA	
	Examiner	Art Unit	
	James Kish	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-44 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-44 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 20 October 2003 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 2/8/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 8-12, 14, 17-20, 22, 25-27, 29-36, and 38-42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 5-9, 11, 17-18, 21-23, 25-32, and 34-38 of copending Application No. 10/621,196. Although the conflicting claims are not identical, they are not patentably distinct from each other because the inventions share an identical scope while only minor limitations exist within the claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-8, 14, 16, 21, and 25-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blume et al.'805 (US Application No. 2001/0021805) in view of McEwan (US Patent No. 6,914,552). Blume'805 discloses a method and apparatus for displaying and using a shaped field of a repositionable magnet to move, guide, and/or steer a magnetic catheter in living tissue. Blume'805 provides a program that instructs a processor to calculate, from localizer inputs that result from fiducial markers, the location and orientation of a magnet to provide the magnetic field. Navigation can occur automatically or manually. Manual navigation would use inputs such as a keyboard, mouse, joystick, or any other input device or devices communicating with the processor (Paragraph [0037]). Also see Paragraph [0015] with respect to fiducial markers, as well as Paragraph [0034]. Paragraph [0039] discusses using fiducial markers in conjunction with CAT, X-ray, or MR images. With regard to claim 4, Paragraph 42 discloses more than one magnet/magnet assemblies can be used. While not directly stated, the processor is capable of being programmed to calculate a position error and

automatically correct for said error. Fluoroscopic imaging is described in Paragraph [0043]. With regard to claim 8, item 42 of Figure 1 shows an operator interface. In regards to claim 14, the system is considered to have an X, Y and Z-axis controller and amplifier in order to appropriately position the catheter. While Blume'805 discusses locating the implanted medical device, there is no mention of doing so via radar. However, McEwan teaches a magneto-radar detector in which a radar detector picks up on slight vibrations of a device being tracked. One embodiment of this system utilizes an ultra-wideband micro power impulse radar (see Abstract). McEwan teaches that the second harmonic is generally the dominant frequency of interest (column 4, lines 6-8). With regard to claim 16, phased arrays are well known in the art (see Conclusion) and it would have been obvious to use such a radar system to permit rapid scanning and abrupt alignment changes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the navigation system of Blume'805 to use a radar system as taught by McEwan because this radar system can potentially track the location of a catheter inserted within a patient undergoing a medical procedure (column 2, lines 27-30).

Claims 35, 37-38 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings (US Patent No. 6,148,823) in view of Colley et al. (US Patent No. 4,354,501), further in view of McEwan (US Patent No. 6,914,552). Hastings discloses an apparatus for magnetically controlling a medical tool being inserted into a patient (Figure 5 and column 4, lines 41-50). A magnetic source is provided in, what

can be considered, a cluster-like arrangement on a C-arm, as seen in Figure 1. Column 5, lines 9-11 discusses an external controller used to guide the magnetic field. The controller is capable of changing the current to control the strength of the field. The C-arm can rotate as described in column 5, lines 39-48. It is reasonable to use any medical device necessary for the given operation to be performed. Therefore, Colley teaches an example of a catheter that includes a piezoelectric ring being used to detect air emboli. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a tool with a piezoelectric ring at the distal end in order to detect air emboli in the use of the apparatus disclosed by Hastings. Neither Hastings nor Colley discuss a radar system to locate the distal tip. However, McEwan teaches a magneto-radar detector in which a radar detector picks up on slight vibrations of a device being tracked. One embodiment of this system utilizes an ultra-wideband micro power impulse radar (see Abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the navigation system of Blume'805 to use a radar system as taught by McEwan because this radar system can potentially track the location of a catheter inserted within a patient undergoing a medical procedure (column 2, lines 27-30).

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blume et al.'805 (US Application No. 2001/0021805) in view of McEwan (US Patent No. 6,914,552), further in view of Galel (US Patent No. 5,492,131). While Blume'805 discloses a servo system, there is no discussion of it being a closed-loop servo system.

Galel teaches a closed-loop servo system being used to automatically navigate a catheter through a patient. Also, closed-loop feedback servo systems are well known in the art and therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the well-known closed-loop servo system as taught by Galel in the system disclosed by Blume'805 in order to automate the navigation of the catheter.

Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blume et al.'805 (US Application No. 2001/0021805) in view of McEwan (US Patent No. 6,914,552), further in view of Kawashima (US Patent No. 4,292,961). Blume'805 discloses a magnetically navigable catheter system. When programmed correctly, the processor is capable of automatically compensating for the dynamic position of an organ with the aid of an auxiliary device (such as X-ray; Paragraph [0043]) and a radar system, while also; the manual input is capable of compensating for such motion. However, Kawashima teaches an apparatus for automatically controlling the position of a device within a cavity. A control mechanism automatically controls the position of the distal portion of the device in the cavity (column 1, lines 56-60). While Kawashima accomplishes the automatic position correction without the use of auxiliary devices, the end result of positioning the distal end of the device with respect to the surrounding cavity/organ is the same and therefore, Kawashima is sited as a function equivalent. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate automatic position compensation as taught by Kawashima so

that no particular skill is required for the insertion of the device into a cavity to allow the device to become available for more frequent use (column 2, lines 4-11).

Claims 12-13, 17, 20, 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blume et al.'805 (US Application No. 2001/0021805) in view of McEwan (US Patent No. 6,914,552), further in view of Blume et al.'580 (US Patent No. 6,014,580). Blume'805 discloses a magnetically navigable catheter system. However, the input devices disclosed do not include a virtual tip. However, Blume'580 teaches a "virtual catheter" used in place of a joystick supplied with a shape similar to an actual magnetic tipped catheter being used for a surgical procedure (column 8, lines 7-19). While there is no mention of providing force feedback, it is well known in the art to incorporate feedback to virtual devices being used to guide medical procedures. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize a virtual tip as taught by Blume'580 to guide the actual catheter. Signals corresponding to the bending of the virtual tip could be sent to the processor, which would then convert the bending to corresponding magnetic fields to be applied to the actual tip that would result in the actual catheter being directed in the surgical procedure in a direction corresponding to the bending of the virtual catheter.

Claims 18-19, 22, 24, 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blume et al.'805 (US Application No. 2001/0021805) in view of McEwan (US Patent No. 6,914,552), further in view of Blume et al.'580 (US Patent No.

6,014,580), in even further view of Green (US Patent No. 5,808,665). Blume'805 and Blume'580 combine to create a catheter magnetically navigable with a virtual catheter. However, tactile feedback to the input device is not mentioned. Green teaches tactile feedback being used in virtual surgical instruments to give the operator more realism (column 11, lines 9-29). It would have been obvious t one having ordinary skill in the art at the time the invention was made to have included tactile feedback, as taught by Green, in the virtual catheter, as disclosed by Blume, in order to provide the operator with the realism necessary to perform surgery.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings (US Patent No. 6,148,823) in view of Colley et al. (US Patent No. 4,354,501), further in view of McEwan (US Patent No. 6,914,552), in even further view of Galel (US Patent No. 5,492,131). Hastings, Colley and McEwan, as combined in the rejection of claim 35 above, discloses an apparatus for magnetically controlling a medical tool having piezoelectric rings at its distal tip and being sensed by a radar system. However, the system is not disclosed as a closed-loop servo system. Galel teaches a closed-loop servo system being used to automatically navigate a catheter through a patient. Also, closed-loop feedback servo systems are well known in the art and therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the well-known closed-loop servo system as taught by Galel in the system disclosed by Hastings in order to automate the navigation of the catheter.

Claim 39-41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings (US Patent No. 6,148,823) as modified by Colley et al. (US Patent No. 4,354,501), McEwan (US Patent No. 6,914,552) and Galel (US Patent No. 5,492,131) as combined in the rejection of claim 36 above, further in view of Blume'805 and Kawashima. Hastings, Colley, McEwan and Galel disclose a closed-loop servo system for magnetically controlling a medical tool having piezoelectric rings at its distal tip and being sensed by a radar system. Blume'805 discloses a magnetically navigable catheter system. When programmed correctly, the processor is capable of automatically compensating for the dynamic position of an organ with the aid of an auxiliary device (such as X-ray; Paragraph [0043]) and a radar system, while also; the manual input is capable of compensating for such motion. However, Kawashima teaches an apparatus for automatically controlling the position of a device within a cavity. A control mechanism automatically controls the position of the distal portion of the device in the cavity (column 1, lines 56-60). While Kawashima accomplishes the automatic position correction without the use of auxiliary devices, the end result of positioning the distal end of the device with respect to the surrounding cavity/organ is the same and therefore, Kawashima is sited as a function equivalent.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have configured the magnet source of Blume as modified by Kawashima on a C-arm as taught by Hastings in order to provide a stronger field for a given magnet. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the navigation system of Blume'805 to use a

radar system as taught by McEwan because this radar system can potentially track the location of a catheter inserted within a patient undergoing a medical procedure. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a tool having piezoelectric rings at the distal end as taught by Colley in the apparatus of Blume as modified by Kawashima in order to detect air emboli in a possible application of the apparatus of Hastings. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a well-known closed-loop feedback servo system as taught by Galel as the type of servo system in Blume as modified by Kawashima in order to provide automated advancement and positioning.

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings (US Patent No. 6,148,823) in view of Colley et al. (US Patent No. 4,354,501), further in view of McEwan (US Patent No. 6,914,552), in even further view of Blume'580. Hastings, Colley and McEwan, as combined in the rejection of claim 35 above, discloses an apparatus for magnetically controlling a medical tool having piezoelectric rings at its distal tip and being sensed by a radar system. However, the input devices disclosed do not include a virtual tip. However, Blume'580 teaches a "virtual catheter" used in place of a joystick supplied with a shape similar to an actual magnetic tipped catheter being used for a surgical procedure (column 8, lines 7-19). While there is no mention of providing force feedback, it is well known in the art to incorporate feedback to virtual devices being used to guide medical procedures. Therefore, it would have

been obvious to one having ordinary skill in the art at the time the invention was made to utilize a virtual tip as taught by Blume'580 to guide the actual catheter. Signals corresponding to the bending of the virtual tip could be sent to the processor, which would then convert the bending to corresponding magnetic fields to be applied to the actual tip that would result in the actual catheter being directed in the surgical procedure in a direction corresponding to the bending of the virtual catheter.

Claims 15 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blume et al.'805 (US Application No. 2001/0021805) in view of McEwan (US Patent No. 6,914,552), further in view of Hunter et al. (US Patent No. 6,381,485). Blume'805 and McEwan, as combined in the rejection of claims 1, 3-8, 14, 16, 25-29, and 31-32 above, discloses an apparatus for magnetically controlling a medical device. However, the fiducial sensors that are used are not disclosed as 6-DOF sensors. Hunter teaches 6-DOF sensors used to register fiducial marker location and orientation between image space and patient space. By registering the medical device in patient space with the aid of the 6-DOF sensors, the processor is capable of being programmed to use this information, as well as the information from the radar system, to correct position errors. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use 6-DOF sensors as taught by Hunter to register the images taken by the auxiliary device with the actual image space.

Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings (US Patent No. 6,148,823) in view of Colley et al. (US Patent No. 4,354,501), further in view of McEwan (US Patent No. 6,914,552), further in view of Hunter et al. (US Patent No. 6,381,485). Hastings, Colley, and McEwan disclose a closed-loop servo system for magnetically controlling a medical tool having piezoelectric rings at its distal tip and being sensed by a radar system. However, the fiducial sensors that are used are not disclosed as 6-DOF sensors. Hunter teaches 6-DOF sensors used to register fiducial marker location and orientation between image space and patient space. By registering the medical device in patient space with the aid of the 6-DOF sensors, the processor is capable of being programmed to use this information, as well as the information from the radar system, to correct position errors. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use 6-DOF sensors as taught by Hunter to register the images taken by the auxiliary device with the actual image space.

Conclusion

Additional Relevant Patents:

Force Feedback:

Rosenberg et al. - 5,821,920

Basdogan et al. – 6,704,694

Massie et al. – 6,853,965

Phase Array:

LaRocca – 5,209,234

Thomas, III et al. – 5,226,847

Erickson – 5,249,163

Seale – 5,844,140

Radar:

Casper et al. – 5,167,626

Silverstein et al. – 5,775,322

Magnetic Surgery Devices:

Werp et al. - 6,015,414

Ritter et al. – 6,241,671

Jin – 6,776,165

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Kish whose telephone number is 571-272-5554. The examiner can normally be reached on 8:30 - 5:00 ~ Mon. - Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JMK

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